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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant : Susumo MUTO et al.

Confirmation No.: 4061

Application No. : 10/517,324 Group Art Unit: not yet assigned
(National Stage of PCT/JP2004/013193)
I.A. Filed : September 3, 2004 Examiner: not yet assigned

For : PLASMINOGEN ACTIVATOR INHIBITOR-1 INHIBITOR

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Pursuant to 37 C.F.R. § 1.56 and 37 C.F.R. §§ 1.97-1.98, Applicants hereby direct the Examiner's attention to the following documents cited in the International Search Report for International Application PCT/JP2004/013193 of which the above-referenced application is a National Stage:

- (1) JP 8-95208 A, April 12, 1996, accompanied by an English language abstract thereof (provided by Patent Abstracts of Japan);
- (2) JP 60-156387 A, August 16, 1985, accompanied by an English language abstract thereof (provided by Patent Abstracts of Japan);
- (3) WO 00/32598 A1, June 8, 2006;
- (4) WO 01/57006 A1, August 9, 2001;
- (5) DE 11 19 436, December 14, 1961, accompanied by an English language abstract thereof (provided by Chemical Abstracts);

(6) WO 2004/024061 A2, March 25, 2004.

Applicants further direct the Examiner's attention to the following documents cited in the present application:

- (7) SCHNEIDERMAN et al. "Increased type 1 plasminogen activator inhibitor gene expression in atherosclerotic human arteries", Proceedings in the National Academy of Science U.S.A., vol. 89 (1992), pp. 6998-7002; Applicants note that this document is cited and discussed in the present specification, beginning at page 2;
- (8) ERICKSON et al. "Development of Venous Occlusions in Mmice Transgenic for the Plasminogen Activator Inhibitor-1 gene", Nature, vol. 346 (1990), pp. 74-76; Applicants note that this document is cited and discussed in the present specification, beginning at page 2;
- (9) SAMAD et al. "Tissue Distribution and Regulation of the Plasminogen Activator Inhibitor-1 in Obese Mice", Molecular Medicine, vol. 2, No. 5 (1996), pp. 568-582; Applicants note that this document is cited and discussed in the present specification, beginning at page 2;
- (10) SCHÄFER et al. "Disruption of the Plasminogen Activator Inhibitor 1 Gene reduces the Adiposity and improves the Metabolic Profile of Genetically Obese and Diabetic ob/ob Mice", FASEB Journal, vol. 15, No. 10 (2001), pp. 1840-1842; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;

- (11) TSUCHIYA et al. "The Antibody to Plasminogen Activator Inhibitor-1 suppresses Pulmonary Metastases of Human Fibrosarcoma in Athymic Mice", General and Diagnostic Pathology, vol. 141 (1995), pp. 41-48; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;
- (12) BAJOU et al. "Absence of Host Plasminogen and Activator Inhibitor-1 prevents Cancer Invasion and Vascularization" Nature Medicine, vol. 4, no. 6 (1998), pp.923-928; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;
- (13) CHO et al. "Production of Plasminogen Activator Inhibitor-1 by Human Mast Cells and Its Possible Role in Asthma", The Journal of Immunology, vol.165, no. 6 (2000), pp. 3154-3161; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;
- (14) OH et al. "PAI-1 promotes Extracellular Matrix Deposition in the Airways of a Murine Asthma Model", Biochemical and Biophysical Research Communications, vol. 294 (2002), pp. 1155-1160; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;
- (15) BJÖRQUIST et al. "Identification of the Binding Site for a Low-Molecular-Weight Inhibitor of Plasminogen Activator Inhibitor Type 1 by Site-Directed Mutagenesis", Biochemistry, vol. 37 (1998), 1227-1234;

- Applicants note that this document is cited and discussed in the present specification, beginning at page 3;
- (16) MITSUNOBU "The Use of Diethyl Azodicarboxylate and Triphenylphosphine in Synthesis and Transformation of Natural Products", *Synthesis* (1981), pp. 1-28; Applicants note that this document is cited and discussed in the present specification, beginning at page 173;
- (17) DÜRÜST "A New and Convenient Synthesis of some Substituted Thiohydantoins", *Synthetic Communications*, vol. 29, no. 11 (1999), pp. 1997-2005; Applicants note that this document is cited and discussed in the present specification, beginning at page 173;
- (18) KOZUMA "Drug Eluting Stent", *Coronary Intervention*, vol. 1, no. 1 (2002), pp. 58-62, accompanied by an English language translation thereof; Applicants note that this document is cited and discussed in the present specification, beginning at page 182;
- (19) HIATT et al. "Drug-Eluting Stents for the Prevention of Restenosis: In Quest for the Holy Grail", *Catheterization and Cardiovascular Interventions*, vol. 55 (2002), pp. 409-417; Applicants note that this document is cited and discussed in the present specification, beginning at page 183;
- (20) CURFMAN "Sirolimus-Eluting Coronary Stents," *New England Journal of Medicine*, vol. 346, no. 23 (2002), pp. 1770-1771; Applicants note

- that this document is cited and discussed in the present specification, beginning at page 183;
- (21) MORICE et al. "A Randomized Comparison of a Sirolimus-Eluting Stent with a Standard Stent for Coronary Revascularization," New England Journal of Medicine, vol. 346, no. 23 (2002), pp. 1773-1780; Applicants note that this document is cited and discussed in the present specification, beginning at page 183;
- (22) WO 95/32190 A2, November 30, 1995; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;
- (23) WO 95/21832 A1, August 17, 1995; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;
- (24) GB 2 372 740 A, September 4, 2002; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;
- (25) WO 03/000253 A1, January 3, 2003; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;
- (26) WO 03/000258 A1, January 3, 2003; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;

- (27) WO 03/000649 A1, January 3, 2003; Applicants note that this document is cited and discussed in the present specification, beginning at page 3;
- (28) WO 03/000671 A1, January 3, 2003; Applicants note that this document is cited and discussed in the present specification, beginning at page 4;
- (29) WO 03/000684 A1, January 3, 2003; Applicants note that this document is cited and discussed in the present specification, beginning at page 4;
- (30) WO 02/064065 A2, August 22, 2002; Applicants note that this document is cited and discussed in the present specification, beginning at page 183.

Copies of the above-listed documents, the International Search Report for International Application PCT/JP2004/013193 (in English) and the International Preliminary Report on Patentability (in English) are enclosed together with a completed copy of the Form PTO-1449 listing these documents. Accordingly, the Examiner is requested to consider these documents and to indicate such consideration by returning a signed and initialed copy of the Form PTO-1449 with the next official communication.

Applicants note that an Office Action on the merits has not yet issued in the instant application, and thus, no fee is necessary to ensure consideration of

this statement. However, if an Office Action has issued and is crossing in the mail with this statement, the Patent and Trademark Office is hereby authorized to charge Deposit Account No. 19-0089 any fee necessary to ensure consideration of the submitted materials.

Should there be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,
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